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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,734	06/14/2000	SILVIU ITESCU	31856-PCT	2918

21003 7590 04/22/2005

BAKER & BOTTS  
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NEW YORK, NY 10112

EXAMINER
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SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/509,734

Applicant(s)

ITESCU, SILVIU

Examiner

David A. Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004 and 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Amendments 11/15/04 and 1/6/05 have been entered; claims 1-7 and 19 are pending and under examination.

The following new grounds of rejection are stated:

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step a) "activated T-lymphocytes" is unclear because one does not know what the T-lymphocytes have been activated by. There are numerous art known activators of T-cells such as certain lectins, PMA, and specific antigens. Absent a statement of what the T-lymphocytes have been activated by or against, the nature of the assaying step b) of claim 1 is unclear.

In claims 7 "the presence of antigen activated lymphocytes" lacks antecedent basis because claim 1 has recited nothing about the lymphocytes being "antigen activated".

It is also unclear as to what kind of "antigen" the lymphocytes of claim 7 have been activated against.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the case in which one determines whether the T-lymphocytes of step b) have been activated against an HLADR antigen of the donor, does not reasonably provide enablement for his case in which one determines whether the T-lymphocytes of step b) have been activated by any non-specific activating agent or by any antigen. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant's disclosure has only shown a correlation between a risk of transplant rejection in the case in which the T-lymphocytes of the recipient are activated against HLA-DR antigens of the donor.

Applicant's disclosure has shown no correlation between risk of transplant rejection and presence of T-lymphocytes that have been non-specifically activated (e.g. by a lectin or PMA), or that have been activated by a totally unrelated antigen (e.g. PPD), or that have been activated by HLA-DR antigens that are not of the type of the donor. Undue experimentation would be required for one to determine whether there would be any correlations between risk of transplant rejection and T-lymphocyte activation by such other agents.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome previously stated rejections of claim 19 under 35 USC 112, first and second paragraphs.

Likewise the amendment has overcome the previously stated prior art rejections over Itescu et al (Circulation, 1998) and Itescu et al (Journal Heart Lung Transplant, 1977).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 273-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR  
March 24, 2005

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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